DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-208

Andrx Pharmaceuticals, LLC
Attention: Janet Vaughn
4955 Orange Drive
Ft. Lauderdale, FL 33314

JAN 28 2004

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 17, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Loratadine and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/120 mg (12-Hour Formulation) (OTC).

Reference is also made to our Tentative Approval letter dated February 24, 2003, and to your amendments dated April 15, and June 16, 2003.

The listed drug product (RLD) referenced in your application, Claritin-D® 12-Hour Extended-release Tablets of Schering Corporation (Schering), is subject to periods of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), U.S. Patent 4,659,716 (the '716 patent) is scheduled to expire on October 21, 2004, and U.S. Patent 4,863,931 (the '931 patent) is scheduled to expire on March 15, 2009. Your application contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Loratadine and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/120 mg (12-Hour Formulation), will not infringe on the claims of the '716 or '931 patents. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately, unless an action is brought against Andrx Pharmaceuticals, L.L.C. (Andrx) for infringement of either the '716 or '931 patents that were the subject of the paragraph IV certifications. This action must be brought against Andrx prior to the expiration of forty-five (45) days from the date the notice provided by Andrx under Section 505(j)(2)(B)(i) was received by the patent and NDA holders.

You have notified the Agency that Andrx complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, in September 2001, Schering initiated a lawsuit alleging

infringement of the '716 patent against you in the United States District Court for the District of New Jersey [Schering Corporation v. Andrx Corporation, Andrx Pharmaceuticals, Inc. and Andrx Pharmaceuticals LLC, Civil Action No. 2:01-CV-04284 (JAG)]. In an order dated August 8, 2002, the Chief Judge of the United States District Court for the District of New Jersey granted the defendant's motion for summary judgement, ruling that the contested claims of the '716 patent were invalid. These were the only claims in this case. We note that on August 8, 2002, Schering appealed the district court's decision in the consolidated case to the United States Court of Appeals for the Federal Circuit. On August 1, 2003, the United States Court of Appeals for the Federal Circuit affirmed the District Court's prior decision finding the contested claims of the '716 patent to be invalid. In addition, we note that no action was brought by either the patent holder or NDA holder against Andrx within the 45-day period with regard to the '931 patent.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for Over-the-Counter (OTC) use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Loratadine and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/120 mg (12-Hour Formulation), to be bioequivalent to the listed drug (Claritin-D® 12-Hour Extended-release Tablets of Schering Corporation). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

(b)(6) [redacted]

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research